

Claims

1. A method for forming a dispersion comprising non-lamellar amphiphile particles having improved phase behaviour, particle size distribution and/or storage stability, said method comprising forming a dispersion of lamellar and optionally non-lamellar particles comprising at least one structuring agent in a polar solvent, heating said particles to an elevated temperature, followed by cooling, wherein said heating is to a temperature and for a period sufficient to provide, after cooling, a measurable improvement in phase behaviour, particle size distribution and/or storage stability.
2. A method for the production of (preferably colloidal) non-lamellar particles, said method comprising forming a dispersion of lamellar and optionally non-lamellar particles comprising at least one structuring agent in a polar solvent, heating said particles to an elevated temperature, followed by cooling, preferably to ambient temperature, wherein said heating is to a temperature and for a period sufficient to provide conversion of at least 50% of said lamellar particles to non-lamellar form, after cooling.
3. A method for narrowing the particle size distribution of a sample of a dispersion of lamellar and/or non-lamellar particles comprising at least one structuring agent in a polar solvent, said method comprising heating said particles to an elevated temperature, followed by cooling, preferably to ambient temperature, wherein said heating is to a temperature

and for a period sufficient to provide a narrowing of said particle size distribution, after cooling.

4. A method for stabilising the particle size distribution (for example, as displayed by light scattering) of a dispersion of lamellar and/or non-lamellar particles comprising at least one structuring agent in a polar solvent, said method comprising heating said particles to an elevated temperature, followed by cooling, preferably to ambient temperature, wherein said heating is to a temperature and for a period sufficient to provide stabilisation of said particle size distribution after cooling.

5. A method for controlling the particle size and/or particle size distribution of a dispersion of lamellar and/or non-lamellar particles comprising at least one structuring agent in a polar solvent, said method comprising heating said particles to an elevated temperature in said polar solvent at controlled ionic strength, followed by cooling, preferably to ambient temperature, wherein said heating is to a temperature and for a period sufficient to provide controll over of said particle size and/ or particle size distribution, after cooling.

6. A method as claimed in claim 5 wherein said polar solvent is a aqueous solution of ionic strength 0.1 to 100mM NaCl or ionic strength equivalent.

7. A method for controlling the particle size and/or particle size distribution of a dispersion of lamellar and/or non-lamellar particles comprising at least one

structuring agent in a polar solvent, said method comprising heating said particles to an elevated temperature at a controlled dilution in said polar solvent, followed by cooling, preferably to ambient temperature, wherein said heating is to a temperature and for a period sufficient to provide control over of said particle size and/or particle size distribution, after cooling.

8. A method as claimed in any of claims 1 to 7 wherein said polar solvent is an aqueous solution.
9. A method as claimed in any of claims 1 to 8 wherein said particles are colloidal.
10. A method as claimed in any of claims 1 to 9 wherein said particles comprise at least 50% of a structure forming amphiphilic component "a", up to 40% of at least one structure swelling agent "b" and up to 20% of a dispersion stabilising polymeric agent "c", wherein all parts are by weight relative to the total weight of a+b+c.
11. A method as claimed in any of claims 1 to 10 wherein said heating is to a temperature of 75 to 200°C.
12. A method as claimed in any of claims 1 to 11 wherein said heating is to an elevated temperature at which the equilibrium form of the particles is not non-lamellar.
13. A method as claimed in any of claims 1 to 11

wherein said heating is to an elevated temperature at which the equilibrium form of the particles is not liquid crystalline.

14. A method as claimed in claim 12 or claim 13 wherein said heating is to an elevated temperature at which the equilibrium form of the particles is L₂ phase.

15. A method as claimed in any of claims 1 to 15 wherein said heating is for a period of between 1 minute and 4 hours.

16. A method as claimed in any of claims 1 to 15 wherein said dispersion of lamellar and/or non-lamellar particles is formed by sonication and/or extrusion.

17. A method as claimed in any of claims 1 to 16 further comprising drying said particles.

18. Amphiphile particles formed by the method of any of claims 1 to 17.

19. Amphiphile particles comprising at least one structuring agent, wherein at least 75% of the particles are non-lamellar.

20. Amphiphile particles as claimed in claim 18 or claim 19 wherein the size distribution of said particles is essentially stable to storage in dispersion in a polar solvent at room temperature for at least 10 days.

21. Amphiphile particles as claimed in claim 18 or claim 19 wherein the size distribution of said particles is essentially stable to storage in dispersion at a concentration of 2% total amphiphile in a polar solvent at room temperature for at least 10 days
22. Amphiphile particles as claimed in any of claims 18 to 21 further comprising at least one active agent.
23. Amphiphile particles as claimed in claim 22 wherein said active agent is selected from human and veterinary drugs and vaccines, diagnostic agents, plant essential oils, plant extracts, aromas, cosmetic agents, nutrients, and dietary supplements.
24. Amphiphile particles as claimed in any of claims 18 to 23 wherein said particles are colloidal.
25. Amphiphile particles as claimed in any of claims 18 to 24 wherein said structuring agent is at least one selected from the group of natural lipids, synthetic lipids, surfactants and copolymers.
26. Amphiphile particles as claimed in claim 25 wherein said structuring agent is at least one selected from the group of glycerol monooleate (GMO), glycerol monolinoleate, diglycerol monooleate (DGMO), diglycerol monolinoleate, glyceryl dioleate, dioleoyl phosphatidyl ethanolamine (DOPE), dioleoyl phosphatidylcholine (DOPC), phytantriol, and mixtures thereof.
27. Amphiphile particles as claimed in any of claims 18

to 26 wherein said particles additionally comprise at least one fatty acid or fatty acid salt.

28. Amphiphile particles as claimed in any of claims 18 to 27 further comprising a fragmentation agent.

29. Amphiphile particles as claimed in claim 28 wherein said fragmentation agent is a polyethylene oxide copolymer, a lipid derivatised with polyethylene oxide, a hydrophobically modified polysaccharide, an amphiphilic protein or a mixture thereof.

30. Amphiphile particles as claimed in any of claims 18 to 29 comprising a structuring agent selected from glycerol monooleate (GMO), diglycerol monooleate (DGM0), glycerol dioleate, dioleoyl phosphatidyl ethanolamine (DOPE) and mixtures of and further comprising a fragmentation agent selected from poloxamer 407, poloxamer 188, TMGO-15, dioleoyl phosphatidyl ethanolamine-polyethyleneglycol (5000), polysorbate 80 and mixtures thereof.

31. Amphiphile particles as claimed in any of claims 18 to 29 wherein said particles comprise at least 50% of a structure forming amphiphilic component "a", up to 40% of at least one structure swelling agent "b" and up to 20% of a dispersion stabilising polymeric agent "c", wherein all parts are by weight relative to the total weight of a+b+c.

32. Amphiphile particles as claimed in any of claims 18 to 31 wherein the equilibrium form of the particles at

room temperature is non-lamellar.

33. A dry powder comprising amphiphile particles as claimed in any of claims 17 to 32.

34. A gel or cream comprising amphiphile particles as claimed in any of claims 17 to 32.

35. A pharmaceutical composition comprising amphiphile particles as claimed in any of claims 17 to 32.